

P201 Meta-analysis of the decision impact of the 21-gene breast cancer Recurrence Score[®] in clinical practice

Predictive and prognostic factors

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Goals: In the European Union, an estimated 322,000 new cases of breast cancer were diagnosed in 2008. The 21-gene Recurrence Score (Oncotype DX Breast Cancer Assay, Genomic Health) is a validated assay to direct the appropriate treatment of oestrogen receptor-positive (ER-positive), early stage breast cancer (ESBC) in the adjuvant setting. To evaluate the overall treatment impact of the 21-gene breast cancer RS, we conducted a meta-analysis of the RS's influence on treatment recommendations and decisions in ER-positive ESBC.

Methods: Results were abstracted on cohort studies that reported the change in the recommendation or actual use of adjuvant chemotherapy (CT) for patients with ER-positive ESBC before and after the RS. Outcomes evaluated were: treatment decision change from (1) Chemohormonal therapy (CHT) to HT-only or (2) HT-only to CHT. Actual treatment change was used when available. The percent difference in chemotherapy (CT) recommendations before and after the RS, with 95% confidence interval and significance, was computed using the McNemar test. Significance of chemotherapy reduction was defined at $p = 0.05$ level; the analysis was performed in STATA 9.2 for Windows (College Station, TX, USA).

Results: Nine studies, with a total of 1154 eligible patients, documented the switch from adjuvant CHT to HT alone after the RS. Two studies (Lo et al., J Clin Oncol. 2010; Albnell et al. ESMO 2010) were defined as prospective analyses. Seven studies were retrospective chart reviews. Before RS testing, 671 (58%) of patients were recommended to be treated with adjuvant CHT; after RS testing, 391 (34%) of patients were recommended to be treated with adjuvant CHT. This resulted in a net reduction of CT recommendation of 24% [95% CI: 21%, 27%]. Overall, the RS led to a 36% change in treatment decisions. RS testing led to a 51% switch in treatment recommendations in patients who were initially recommended adjuvant CHT. RS testing led to a 13% switch in treatment recommendations in patients who were initially recommended HT only.

Conclusion: The adoption of the 21-gene RS consistently directs adjuvant treatment decisions from CHT to HT in the nine reported decision impact studies. In addition, the RS will direct treatment switch from HT to CHT in a small percentage of patients. Overall, the RS influenced more than one-third of total treatment decisions.